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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,079	07/11/2006	James Knox Russell	PHUS040020US2	6955

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EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
4123	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,079	RUSSELL ET AL.	
	Examiner	Art Unit	
	Nicole F. LaVert	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

1. The disclosure is objected to because of the following informalities: a) In reference to the phrase, "…electronic module 140 include.." the "include" should be changed to "includes," (pp 10, line 13), b) In respect to the phrase,"…to microprocessor 40," the reference number "40" should be changed to "142," (pp 10, line 26), c) the specification is lacking the necessary headings as set forth above. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. **Claims 1-26** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 & 18 recites the limitation "the physical activity" in regards to the detection of a sensor. There is insufficient antecedent basis for this limitation in the claims.

Claims 3 & 4 recites the limitation "the physiological characteristic sensor" in regards to sensing cardiac signals. There is insufficient antecedent basis for this limitation in the claims.

Claim 9 recites the limitation "the activity level" in regards to the detection of a sensor. There is insufficient antecedent basis for this limitation in the claim.

Claims 9, 11 & 17 recites the limitation "the patient" in regards to subject of testing. There is insufficient antecedent basis for this limitation in the claims.

Claim 11 recites the limitation "the threshold" in regards to generating a baseline of information. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "the occurrence of class 1 arrhythmia event" in regards to the threshold detector. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-4, 6, 8, 9-12, 14, 16-17, 18, 21-22, 23, & 24-26** are rejected under 35 U.S.C. 102(b) as being anticipated by Nolan et al. (US 5,404,877).

For **claim 1**, Nolan et al. discloses, a physiological monitoring system which comprises (col 1, lines 8-15): at least one sensor for detecting a biological signal, representative of a physiological characteristic of a monitor-wearing patient and generating an electrical signal representative of the biological signal (col 3, lines 28-44); at least one sensor for detecting the physical activity of the patient and generating an electrical signal, representative of physical activity (col 4, lines 16-19); processing means, coupled to said sensors for processing said electrical signals [(col 5, lines 50-62) & (col 8, lines 49-54)]; an activity threshold detector coupled to said processing means for receiving said electrical signals representative of physical activity [(col 3, lines 32-44) & (col 4, lines 16-19) ; a user interface for communicating information about the detected biological signal to the patient (col 9, lines 10-22); means for controlling the communication of information in response to detection of an activity threshold by said activity threshold detector [(col 3, lines 32-44), (col 4, lines 16-19) & (col 9, lines 23-39)].

In reference to **claim 2**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), further comprising a means for programming said physical activity sensor for operational control at a selected threshold of physical activity (col 4, lines 16-19).

In reference to **claim 3**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), wherein the physiological characteristic sensor is adapted to sense cardiac signals (col 3, lines 28-44).

In reference to **claim 4**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), wherein the physiological characteristic sensor (col 3, lines 28-44) comprises electrocardiography electrodes that detect biological signals representative of the heart beats of the patient (col 2, lines 9-14).

In reference to **claim 6**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), wherein the physical activity sensor (col 4, lines 16-19) comprises an accelerometer, a pedometer, an electrical noise detector, electronic capacitive sensor, an electromyographic sensor, a skin impedance sensor [(col 3, lines 45-49) & (col 4, lines 51-53)], or a piezoelectric sensor.

In reference to **claim 8**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), further comprising a means for wireless transmission of information about the detected biological signal or system functions to a receiver external to the system (col 9,lines 23-39).

For **claim 9**, Nolan et al. discloses, an ambulatory electrocardiography monitoring system for recording electrocardiography signals from a patient (col 2, lines 21-25), comprising: a plurality of sensors for detecting a plurality of biological signals (col 2, lines 32-36), each biological signal representative of a physiological characteristic of a monitor-wearing patient (col 3, lines 28-44), wherein at least one sensor comprises at one or more electrocardiography electrodes that sense electrocardiography signals from a patient (col 2, lines 9-14) and at least one sensor that detects the activity level of the patient (col 4, lines 16-19), whereby the sensors generate an electrical signal representative of each respective biological signal (col 3, lines 28-44); an arrhythmia threshold detector coupled to the electrocardiography sensor (col 5, lines 54-60) for receiving said electrical signals representative of the electrocardiography signals and

determining whether the signals are below or above a preset threshold (col 3, lines 60-66); an activity threshold detector coupled to the activity sensor for receiving said electrical signals representative of the activity level of the patient and determining whether the signals are below or above a predetermined threshold [(col 3, lines 60-66) & (col 4, lines 16-19)]; a system error detector for detecting system errors and determining if the error meets pre-determined criteria (col 9, lines 4-22); a processor for controlling the communication of system and biological signal information to the patient [(col 5, lines 50-62) & (col 8, lines 48-50)] through a user interface (col 9, lines 10-22) based on the detection of an activity threshold by said activity threshold detector [(col 3, lines 60-66) & (col 4, lines 16-19)], arrhythmia threshold by said arrhythmia threshold detector (col 5, lines 54-60), and/or system errors by the system error detector (col 9, lines 4-22).

In reference to **claim 10**, Nolan et al. discloses, the system of claim 9 (col 2, lines 21-25), wherein the user interface comprises an alarm circuit comprising acoustic, tactile, or visual modes of communicating information to the patient (col 9, lines 10-22), and mode is determined by processor based on whether the signals from the respective detectors meet pre-determined thresholds [(col 3, lines 60-66) & (col 8, lines 48-50)].

In reference to **claim 11**, Nolan et al. discloses, the system of claim 9 (col 2, lines 21-25), wherein processor further comprises a calibration means (col 9, lines 40-54) for setting the threshold of the arrhythmia threshold detector (col 5,lines 50-62) based on processing of electrocardiography signals from the patient to generate a baseline of electrocardiography information [(col 8, lines 48-62) & (col 9, lines 40-54)].

In reference to **claim 12**, Nolan et al. discloses, the system of claim 9 (col 2, lines 21-25), wherein the threshold of the arrhythmia threshold detector [(col 3, lines 60-66) & (col 5, lines 50-62)] is pre-programmed into a memory component of the system (col 8, lines 50-63).

In reference to **claim 14**, Nolan et al. discloses, the system of claim 9 (col 2, lines 21-25), wherein the physical activity sensor (col 4, lines 16-19) comprises an accelerometer, a pedometer, an electrical noise detector, electronic capacitive sensor, an electromyographic sensor, a skin impedance sensor [(col 3, lines 45-49) & (col 4, lines 51-53)], or a piezoelectric sensor.

In reference to **claim 16**, Nolan et al. discloses, the system of claim 9 (col 2, lines 21-25), wherein the arrhythmia threshold detector is set at a pre-determined threshold to detect the occurrence of class 1 arrhythmia event [(col 3, lines 60-66) & (col 5, lines 50-62)].

In reference to **claim 17**, Nolan et al. discloses, the system of claim 9 (col 2, lines 21-25), further comprising means of wireless communication to an external system, for communication of information about the patient and system state to the patient or to others (col 9, lines 23-39).

For **claim 18**, Nolan et al. discloses, a method for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising (col 1, lines 8-15): attaching a physiological monitoring system to a patient (col 5, lines 50-56); sensing one or more selected physiological parameters of the patient (col 5, lines 50-62); sensing the physical activity of the patient (col 4, lines 16-19); comparing the sensed physical activity to a pre-set threshold to determine whether the physical activity exceeds the threshold [(col 3, lines 60 –66) 7 (col 4, lines 16-19)]; detecting a system error to be communicated to the patient and determining whether the detected error meets pre-determined criteria; generating an error signal

based on the system error and transmitting the error signal to the patient via a user interface (col 9, lines 4-22), if the physical activity of the patient exceeds the pre-set threshold [(col 3, lines 60 -66) 7 (col 4, lines 16-19)].

In reference to **claim 21**, Nolan et al. discloses, the method of claim 18 (col 1, lines 8-15), wherein the selected physiological parameter of the patient is sensed by at least one sensor comprising (col 3, lines 28-44) two or more electrocardiography electrodes that sense electrocardiography signals from the patient (col 2, lines 32-36), whereby the sensor generates an electrical signal representative of the selected physiological parameter (col 3, lines 28-44).

In reference to **claim 22**, Nolan et al. discloses, the method of claim 18 (col 1, lines 8-15), wherein the physiological parameter comprises electrocardiography signals (col 2, lines 21-28) and the threshold of the selected physiological parameter of the patient is detected by an arrhythmia threshold detector [(col 3, lines 60-66) & (col5, lines 50-62)] that determines whether the sensed electrocardiography signals (col 2, lines 23-25) are below or above a selected threshold representing an arrhythmic event [(col 3, lines 60-66) & (col5, lines 50-62)].

For **claim 23**, Nolan et al. discloses, a method for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising the steps of (col 1, lines 8-15): attaching a physiological monitoring system to a patient (col 5, lines 50-56); detecting a selected physiological parameter of the patient (col 5, lines 50-62); sensing the physical activity of the patient (col 4, lines 16-19); detecting a selected threshold of the physical activity of the patient [(col 3, lines 60-6) & (col 4, lines 16-19)]; comparing the detected physiological parameter with pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition (col 3, lines 60-66); generating an alert signal if the

physiological condition of the patient reflects an alarm condition (col 5, lines 50-62); and transmitting the signal to the patient via a user interface, if the physical activity of the patient is below the selected threshold [(col 3, lines 60-66) & (col 9, lines 10-22)].

For **claim 24**, Nolan et al. discloses, a physiological monitoring system comprising (col 1, lines 8-15): at least one sensor for detecting a biological signal of a patient (col 3, lines 28-44); at least one sensor for detecting physical activity of the patient (col 4, lines 16-19); a processor for comparing the detected biological signal with biological signal threshold data (col 8, lines 50-56) and generating a biological signal alarm condition if the threshold is met (col 5, lines 50-62); and an alarm system that produces at least two different types of alarms (col 9, lines 10-22) based on the biological signal alarm condition and the physical activity of the patient [(col 3, lines 49-59) & (col 4, lines 16-19)].

In reference to **claim 25**, Nolan et al. discloses, the physiological monitoring system of claim 24 (col 1, lines 8-15) wherein the alarm system further bases the alarm type on any detected system malfunctions (col 9, lines 10-22).

In reference to **claim 26**, Nolan et al. discloses, the physiological monitoring system of claim 24 (col 1, lines 8-15) wherein the at least one sensor is worn by the patient (col 5, lines 50-56).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claims 5, 7, 13, 15 & 19-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan et al. (US 5,404, 877) in view of Toda et al. (US 20020036446).

Nolan et al. shows all of the features of the instantly claimed invention as discussed above.

Nolan et al. fails to disclose the use of a sensor, which comprises a transducer including a piezoelectric element.

Toda et al. teaches a piezoelectric transducer with a piezoelectric polymer provided with electrodes on its surface [0001].

It would have been obvious to one of ordinary skill in the sensor art to have modified Nolan et al. with the use of a piezoelectric transducer, as taught by Toda et al., in order to provide an effective excitation of acoustic energy [Toda, 0001].

In reference to **claim 5**, Nolan et al. in view of Toda teaches, the system of claim 1 (Nolan, col 1, lines 8-15), wherein the physical activity sensor (col 4, lines 16-19) comprises a transducer [Toda, 0001] that detects chemical, electrical or mechanical characteristics of a monitor-wearing patient (Nolan, col 3, lines 28-44), representative of physical activity, including vibrations, motion, acceleration, electromyographic impulses, or sound impulses (col 4, lines 16-19).

In reference to **claim 7**, Nolan et al. in view of Toda teaches, the system of claim 1 (Nolan, col 1, lines 8-15), wherein the physical activity sensor (col 4, lines 16-19) is a passive transducer including a piezoelectric element [Toda, 0001].

In reference to **claim 13**, Nolan et al. in view of Toda et al. teaches, the system of claim 9 (Nolan, col 1, lines 8-15), wherein the physical activity sensor (col 4, lines 16-19) comprises a

transducer [Toda, 0001] that detects chemical, electrical or mechanical characteristics of a monitor-wearing patient (Nolan, col 3, lines 28-44), representative of physical activity (col 4, lines 16-19).

In reference to **claim 15**, Nolan et al. in view of Toda et al. teaches, the system of claim 9 (Nolan, col 1, lines 8-15), wherein the physical activity sensor (col 4, lines 16-19) is a passive transducer including a piezoelectric element [Toda, 0001].

In reference to **claim 19**, Nolan et al. in view of Toda et al. teaches, the method of claim 18 (Nolan, col 1, lines 8-15), wherein the physical activity sensor (col 4, lines 16-19) comprises a transducer [Toda, 0001] that detects pre-determined chemical, electrical or mechanical characteristics of a monitor-wearing patient (Nolan, col 3, lines 28-44) that are representative of physical activity, wherein the characteristics comprise vibrations, motion, acceleration, electromyographic impulses, or sound impulses (col 4, lines 16-19).

In reference to **claim 20**, Nolan et al. in view of Toda et al. teaches, the method of claim 18 (Nolan, col 1, lines 8-15), wherein the physical activity sensor (col 4, lines 16-19) comprises an accelerometer, a pedometer, a noise detector, electronic capacitive sensor, an electromyographic sensor, or a piezoelectric sensor [Toda, 0001].

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole F. LaVert whose telephone number is 571-270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N.F.L.

/Joseph S. Del Sole/
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